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ELECTRODES FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

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Section A: Clinical Collaboration

A.1 Primary Collaborator Meetings

In the past quarter, meetings were held with primary collaborators from both the upper extremity (P.H. Peckham, Ph.D. and K. Kilgore, Ph.D.) and the lower extremity (E.B. Marsolais, M.D.) research groups in Cleveland. Both collaborator groups indicated a desire for reliable, safe, easy to implant cuffs and a willingness to participate in their clinical implementation.

Spiral cuff electrodes hold promise for application in both upper and lower extremity neural prostheses, even though the specific needs of each group are distinct. The upper extremity group initially expects that a nerve cuff electrode would be placed around the ulnar and possibly median nerves. Selective activation of those nerves would be desired, requiring a multiple contact electrode. In contrast, the lower extremity group expects that nerve cuff electrodes would be needed for several individual muscles in the leg. Graded contractions of those muscles would be generated. This would not require any added selectivity and single contact electrodes could be used. Additionally, the implant technique for the two groups differs. An open procedure, similar to the current implant technique of the upper extremity group, would be followed to implant cuff electrodes in the arm. In the lower extremity group, however, nerve cuff electrodes would need to be implanted endoscopically. This would require design and fabrication of an implant tool and development of the endoscopic implant technique.

Additional meetings are planned with both groups. These meetings would expand to include the surgeon(s) and other members of the research teams. The implant sites and techniques will be discussed with the intent of establishing procedures for implanting nerve cuff electrodes. We will work to better identify the clinical opportunities and patient population where these cuffs would first be studied.

Section B: Electrode Design and Fabrication

B.3 Electrode Materials

Abstract

The nerve cuff electrodes being developed under this contract are fabricated from silicone rubber (both sheeting and elastomer) and have lead wires that are insulated in fluoropolymer. The availability of both of these materials has been effected by recent business decisions of two major material suppliers. Alternative material sources have been identified, but the equivalence of these materials in our cuff electrodes has not been established in terms of either mechanical performance or tissue response. A series of in vivo tests on rats has been proposed to test the biological response to both the silicone rubber and fluoropolymer materials proposed as replacements. A discussion of the materials to be studied and the method to be followed in the animal protocol is presented here. The implants are expected to begin in the next quarter.

Silicone Rubber

Cuff electrodes have been developed in our laboratory over the last 10 years using materials with an established implant history and widespread availability. In fabricating the self-wrapping cuffs, a layer of silicone rubber elastomer is sandwiched between a layer of unstretched and a layer of stretched silicone rubber sheeting and the assembly is bonded together. During the development of the cuffs, the silicone rubber sheeting has been acquired from two different sources: directly from Dow Corning and from a processor (SciMed Surgical) of Dow Corning material (Silastic Q7-4550). The material used to bond the sheeting has been Dow Corning's Silastic MDX4-4210 elastomer.

Dow Corning materials are no longer authorized to be used for implants of greater than 29 days. Efforts have been made to identify other material suppliers and processors in order to acquire elastomer and sheeting that can be used in the manufacture of cuff electrodes intended for long-term implant.

Elastomer

The elastomer previously used in our lab both in fabricating cuffs and in some molding applications has been Dow Corning's Silastic MDX4-4210. An elastomer with similar reported properties has been purchased from NuSil Silicone Technology (MED4-4210), and has been used in our lab to bond sheeting and to mold components. On one occasion during our use of the material, the sheets of a cuff did not bond, but it is unclear whether the cause of that failure was the elastomer or a manufacturing error. In all other instances, the new material has behaved as was anticipated from experience with the Dow Corning elastomer. Anecdotal observations are that the

replacement material (NuSil's MED4-4210) is more viscous and sets up quicker than the original material (Dow's MDX4-4210). Once cured, however, no observable differences have been noted between the NuSil and the Dow Corning products. No quantitative evaluation of the material in any of our applications has yet been performed.

Sheeting

In the past, we have purchased silicone rubber sheeting directly from Dow Corning and more recently from another processor. That processor (SciMed Surgical) has supplied sheeting to us in 1, 2 and 3 mil thicknesses using Dow Corning's Silastic Q7-4550 formulation. That supplier processes strictly Dow Corning materials for a non-implant application. Therefore, both an appropriate alternative raw material and an alternative material processor for sheeting in this small thickness range needed to be identified.

A contract manufacturer in California was identified and contacted to fabricate silicone rubber sheeting. Three different kinds of sheeting have been purchased from Specialty Silicone Fabricators, using three different NuSil material formulations. Originally, the use of two different high consistency silicone rubber formulations were specified for the fabrication of 2 and 3 mil thick sheeting. The fabricator was to calender the material into a continuous roll of sheeting. Problems were encountered with the processibility of the materials and the fabricator was only able to deliver 3 mil thick sheeting made from one of the high consistency silicone rubber formulations.

It was then recommended by both the material supplier and the material processor that a liquid dispersion silicone rubber formulation be used to fabricate the sheeting. Both companies felt that a liquid dispersion, by nature, would be more likely to be successfully processed into thin sheeting (<3 mil thick). The fabricator was able to use a knife-coating process to fabricate sheeting from the dispersion into a continuous roll of 2 mil thick material.

In handling the material and in fabricating cuffs made from these two new sheeting materials, it was observed that the surface of the sheeting was tacky. Handling was more difficult than expected as the material had a tendency to stick to itself and did not easily peel apart. The material supplier and fabricator were contacted regarding this problem. It was recommended that a slightly modified liquid dispersion formulation be used to make the sheeting. This modified formulation includes a surface flattening agent that has been used before to reduce tackiness on the material surface. Another order was placed, and 2 mil thick sheeting made from this liquid dispersion formulation has recently been received.

All three new formulations of sheeting have been used to make at least one cuff. In addition to having a different surface 'feel' than the sheeting made from Dow's Q7-4550, all of the sheetings seem to have different mechanical properties than the old sheeting. Most notably, the sheeting seems to stretch easier (have a lower modulus) than the sheeting from

SciMed Surgical. This would indicate that the materials are less stiff, which would improve their mechanical compliance as nerve cuffs.

As discussed above, the biggest detriment observed on the new sheeting was the stickiness of the surface, which not only led to increased debris pick-up, but also made the sheeting more difficult to handle. A tacky surface presents a problem not only in handling and fabrication, but may effect the self-sizing of the cuff as the wraps may stick on themselves, preventing free opening and closing of the cuff. The third order of sheeting was placed to address this, and anecdotal observations to date are that the material is distinctly less tacky than the previous two orders.

Fluoropolymer Wire Insulation

The multi-stranded wire used in our electrode lead wires is insulated in an extruded fluoropolymer. This material was originally specified to be FEP (fluorinated ethylene propylene) fluoropolymer based on the material's properties, fabricability, availability and previous use in implants. The company which extruded the insulation onto our wire uses DuPont resins, and the wire has been coated with FEP Teflon (a DuPont trademark). DuPont no longer authorizes the general use of their materials for long-term implants.

FEP fluoropolymer has performed well in our application. We have been told by other extruders that very little FEP is available that is not DuPont resin, and what is available is costly. Another formulation of fluoropolymer, perfluoroalkoxy (PFA) has very similar properties to FEP and is more affordably available. Additionally, this material has slightly improved processing properties which allow it to be extruded to smaller thicknesses. Other extruders have been identified that are able to provide PFA wire insulation in resins not supplied by DuPont. Multi-stranded wire insulated in PFA fluoropolymer has been ordered and received.

PFA is so similar to FEP that the standard inspection procedures performed by our lab on incoming wire batches (see QPR #4, contract NO1-NS-0-2395) has been inadequate to distinguish the two materials. No significant differences in the behavior or properties of the insulated wire have been observed beyond normal, batch to batch variance. Melting temperature, as determined using a Differential Scanning Calorimeter, is a simple way to distinguish PFA from FEP (PFA melts at approx. 300-310°C, FEP melts at approx. 260-275°C). This test has been added to the inspection procedures of newly received wire orders.

Wire coated with PFA insulation has been used in our lab and others for some time. No significant differences have been observed between the behavior of this wire as compared to FEP insulated wire. The material has been used in chronic animal implants performed in our lab. In none of those long-term implants was the biological response to the insulation material specifically studied. While no toxic effects of the material have been observed, a direct comparison between the response to this material, PFA, and the previously used material, FEP, has not yet been made.

In Vivo Study

A study has been proposed to investigate the biological response to both the silicone rubber and fluoropolymer materials discussed above as replacements to those no longer available. Insulated wire segments and silicone rubber nerve cuff electrodes will be implanted using aseptic technique in anesthetized, adult rats.

Silicone rubber nerve cuff electrodes without contacts will be placed around the sciatic nerve of both hind limbs in the rat. The right leg will have a cuff made from Dow Corning material, while the left leg will have a cuff made from NuSil material. In half of the animals, the cuff will also consist of short segments of lead wire that will be run subcutaneously up the animal's leg. The biological response to the cuff materials will be evaluated by histological evaluation of the encapsulation tissue. The effects of the lead cable as well as the stiffness and mechanical compliance of the different sheeting materials will be investigated by evaluating nerve fiber morphology.

Both FEP and PFA insulated wires will be inserted subcutaneously along the back of the rat with the aid of hypodermic needles. Each rat will be implanted with 2 pieces of each material, one short (1 cm) and one long (7 cm). Half of the animals will receive coiled wire implants and half will receive straight wire implants. In this way, any mechanical effects that might influence the inflammatory response to the wire implants can be investigated. Three days before they are to be killed, some of the animals will receive an additional implant. This implant will be two short pieces of straight insulated wire, one of PFA and one of FEP. In this way, the acute response to these two materials can be studied.

Additionally, a number of animals will receive subcutaneous implants of long segments of coiled, insulated wire placed inside silicone rubber tubing. This type of lead configuration is currently used by some researchers in neural prostheses implants (Peckham in the upper extremity). By including these 'closed helix' lead segments, a comparison can be drawn between the expected response to all three materials (FEP insulation, PFA insulation, silicone rubber tubing) and between the two different lead configurations (closed vs. open helix).

After the implant procedure, the animals will be maintained for 2 or 4 weeks. At the end of the implant time, the animals will be killed by aortic perfusion. Following the perfusion, the implants and the tissue surrounding them will be excised and placed in fixative solution. Samples will be prepared and stained for histological evaluation of the encapsulation tissue and nerve fiber morphology.

Future Work

The cuff and wire implants have been fabricated, cleaned, packaged and sterilized. The animal protocol has been approved by the institution and implants are scheduled for the coming quarter.

Section C: Assessment of Electrode Performance in an Animal Model

C.1.b Performance Testing in Chronic Animal Experiments
Neural and Connective Tissue Response to Chronically Implanted Multiple Contact Nerve Cuff Electrodes

The purpose of this project is to document the tissue response to long-term presence of multiple contact spiral nerve cuff electrodes. The electrodes were not chronically stimulated (stimulated only during regular testing intervals, see QPR #7), thus this is an evaluation of passive implants.

Methods

Spiral nerve cuff electrodes, containing 12 individual platinum electrode contacts, each with its own lead, were chronically implanted on the right sciatic nerve of 7 adult cats. All animal care and experimental procedures were according to NIH guidelines and were approved by the Institutional Animal Care and Use Committee of Case Western Reserve University. We have reported previously (QPR #7) on the recruitment properties of these cuffs during the implant period. At the conclusion of the implant period, which ranged from 28-34 weeks, animals were perfused for preservation of the tissue. Animals were initially anesthetized with Ketamine (30 mg/kg, IM), and maintained at a deep level of anesthesia with sodium pentobarbital (5-10 mg bolus injections, IV). The chest was opened and the pericardium cut away. Heparin (1000 units) was injected into the left ventricle and allowed to circulate for 1 minute. A stiff Teflon exit catheter was inserted into the right atrium, while a steel catheter connected to flexible tubing was inserted into the aorta at its exit from the left ventricle. The perfusion consisted of 0.5 L of saline (37°C), 1.0 L of 1% paraformaldehyde in 0.25M sodium cacodylate buffer (pH 7.35) at 37°C, and 2.0 L of 4% glutaraldehyde 0.25M sodium cacodylate buffer (pH 7.35), 1 at 37°C and 1 at 20°C, at an infusion rate of approximately 0.5 L/min. The implanted nerves, cuffs, and surrounding tissue were excised and immersion fixed for 24 hrs in glutaraldehyde at 20°C, and stored in cacodylate buffer until blocking for histological processing.

Nerve tissue samples were post-fixed in a 1:1 solution of cacodylate buffer and 2% osmiun tetroxide in H_20 at room temperature for 4-5 hours. Tissue was dehydrated in acetone series and embedded in low viscosity Spurr resin. Thin sections (1 μm) were cut, mounted on slides, stained with methylene blue borax, and coverslipped. Encapsulation tissue samples were dehydrated in alcohol series and embedded in paraffin. Thick sections (10 μm) were cut, mounted on slides, stained with either Masson's trichrome or hematoxylin and eosin, and coverslipped.

Results

The implant duration ranged from 28-34 weeks (30.6±2.3 weeks, mean±s.d). In three cases the animals accessed and destroyed by pulling and

chewing the percutaneous lead cable within 4 weeks after implant. One additional lead cable was destroyed at 17 weeks post-implant. The three remaining implants functioned for 28, 31, and 32 weeks without failure. All animals maintained normal activity patterns for the duration of the implant. All animals except one (#946) were walking normally within 24 hours after implant, and thereafter maintained normal mobility and behavior. Cat 946 exhibited a "drop foot" in the implanted leg characterized by external rotation of the paw and dragging of the toes during walking. This condition appeared most severe 2 days after implant, and improved steadily thereafter. The toes no longer dragged 7 days post-implant, and gait was entirely normal by 12 days post-implant. In all other cases observation indicated normal gait patterns and the neurological tests revealed no abnormalities.

Encapsulation Tissue

At the time of explant the cuff and lead cable were surrounded by fibrous tissue encapsulation. The connective tissue layer between the cuff and the nerve was 50-300μm thick and consisted of fibroblasts, collagen, and leukocytes. The outer encapsulation ranged from 50μm to 1mm thick, and consisted of a higher proportion of collagen and inactive fibroblasts, and fewer leukocytes than the inner encapsulation tissue. The response at the end of the cuff was typically the region that showed the thickest encapsulation tissue.

Cuff Geometry

In four cases the cuff had a spiral configuration around the outside of the nerve trunk. In one case the inner edge of the cuff had penetrated the epineurium such that two small fascicles lay between the innermost and second wraps of the cuff. In two cases the cuff was in a "double-barrel" configuration at the time of explant. In one of these implants the fourth set of electrodes, furthest from the inner edge of the cuff were no longer in contact with the nerve trunk, although in the other case all four tripoles maintained contact with the nerve trunk.

Neural Tissue

All nerve sections 2 cm proximal to the cuff appeared normal. At the level of the cuff, small regions of one fascicle in each of two nerves exhibited abnormal appearance. Morphological changes included thinly myelinated axons, proliferation of endoneurial connective tissue, and perineurial thickening. In both cases the nerves looked normal distal to the cuff indicating that the changes were localized to small regions within the cuff. Three of the seven implants exhibited morphological changes distal to the cuff electrode, however, the cuff-level sections and proximal sections of these 3 nerves all appeared normal. Morphological changes were characterized by perineurial thickening, scattered thinly myelinated axons, proliferation of endoneurial connective tissue, and an apparent increase in the ratio of small diameter nerve fibers to large diameter nerve fibers.

Future Work

Histological analysis of the explanted tissue will continue. This will include analysis of the morphology of the individual branches of the sciatic nerve over several cm distal to the cuff. The presence of morphological changes will be correlated with the cuff geometry, the electrophysiological results reported previously (QPR #7), and also with trauma induced by the animals pulling on the lead wires.

Section C: Assessment of Electrode Performance in an Animal Model

C.1.b Performance Testing in Chronic Animal Experiments
Analysis of Electrodes

Abstract

Spiral nerve cuff electrodes used in chronic animal experiments were evaluated microscopically for evidence of corrosion. Evaluation methods were similar to those followed in evaluating electrodes which underwent in vitro stimulation (see QPRs #4-7). No significant corrosion was found on any contacts from the chronically implanted electrodes. Observations of the condition of the platinum foil contacts and weld zones were otherwise similar to those made with the in vitro electrodes. In one instance, corrosion was found on a single strand of wire welded to a platinum contact.

Implanted Electrodes

Twelve-contact spiral nerve cuff electrodes were implanted on the sciatic nerve of 6 adult cats for periods of 28-32 weeks. Upon explant from the animal and removal of the encapsulation and neural tissue, the cuffs were prepared for microscopic examination. All 6 cuffs had been cut into 2 or more pieces during tissue removal, but each contact was identified based on its location within the cuff. In some of the cuffs, fewer than 12 contacts remained, as some animals damaged their electrodes (ripped out contacts and/or lead wires) during the implantation period and as some contacts were lost during tissue removal.

To clean the cuff of adherent debris and tissue, the electrodes were ultrasonically cleaned for several minutes in a saturated solution of Biz detergent. The cuff was first cleaned in its relaxed, closed position, and was then held open using a locking forcep to be re-sonicated in the Biz solution.

After having cleaned each cuff, the contacts were individually excised from the silicone rubber sheeting. The locking forcep was used to hold the cuff open and facilitate contact removal. Working under a dissecting microscope, the sheeting around the contact was cut with a scalpel blade, and the contact was removed with forceps. Where possible, the contact was pulled out by grabbing the attached lead wire and not actually contacting the platinum with the forcep. Each of the contacts (with attached lead wire) was placed in an individual, capped tube and labeled based on its position within the cuff.

The contacts were then cleaned again to remove any remaining tissue, debris, elastomer, etc. Contacts were individually sonicated for a minimum of 1 minute each in successive solutions of Biz detergent, water, and ethanol. The contact was then laid on a clean room wiper under the laminar flow hood, allowed to dry, and mounted on an SEM stage. The Biz, water rinse, and ethanol solutions were changed between contacts from each cuff.

The contacts removed from the cuffs and available for evaluation are summarized below. The labels given to each contact denote their position in tripole #0, 1, or 2, and specify the position 0°, 90°, 180° or 270° around the cuff. As discussed above, not all 12 contacts were recovered or available for evaluation.

Cat #946			
0-0	0-90	0-180	0-270
	1-90	1-180	1-270
2-0	2-90	2-180	2-270
Cat #947			
0-0	0-90	0-180	0-270
	1-90	1-180	1-270
2-0	2-90	2-180	2-270
Cat #852			
0-0	0-90	0-180	0-270
1-0	1-90	1-180	1-270
2-0	2-90	2-180	2-270
Cat #894			
0-0	0-90	0-180	0-270
1-0	1-90	1-180	1-270
2-0	2-90	2-180	2-270
Cat #865			
0-0		0-180	
1-0		1-180	
2-0	2-90		
Cat #872			
			0-270
		1-180	

Microscopic Evaluation

The contacts were mounted on SEM stages, sputter coated with palladium, and examined using a scanning electron microscope. Although the contacts were examined primarily for evidence of corrosion, observations of the general condition of the contacts, including surface appearance, shape, welding effects, etc. were made as had been done with contacts from the in vitro stimulated electrodes (see QPRs #5-7).

Size and Shape of Contacts

As seen with the contacts from the in vitro testing, the effects of hand cutting the contacts out of the platinum foil were again observed. The edges of all of the contacts showed some sort of non-uniformity and irregularity, as shown in Figure 1. In some cases, this was evidenced by rough edges and extra ridges of platinum extending along an entire edge. At the corners of several contacts either missing or excess 'toes' of material were found, as though the platinum contact had torn during removal from the sheet of foil.

In many cases, the contact was not square, being either longer on a single edge or being skewed like a parallelogram. The size of the contacts varied from the nominal 1.0 mm on a side, as was also found in the in vitro study. Lengths of a side of the contact ranged from 0.78 - 1.18 mm, with the widest variance in a single contact being 0.2 mm. Contacts from the same cuff tended to be more consistent in size compared to the entire sample set, i.e. the larger contacts were generally from the same cuff and the smaller contacts were generally from another cuff.

Effects of Window Cutting

During fabrication, small windows were cut through the inside layer of silicone rubber to expose the platinum foil contacts. A sharpened section of hypodermic tubing was used to cut the windows. The size of the tubing was reported to be 0.5 mm in diameter.

Gouging from the tool used to cut the window was seen on all but one contact from these electrodes. This type of gouging was found in the in vitro study as well. The deeper and more extensive gouging marks were found on contacts from three cuffs, while the gouging on the remaining three cuffs was judged to be less severe. This seems to indicate either a difference in force used to cut the windows from cuff to cuff, or a difference in the sharpness of the window tool.

Using the gouge marks, the diameter of the window was estimated and compared to the nominal 0.5 mm. The size of the windows ranged from 0.31-0.60 mm in diameter. In a single cuff (#946), 7 of the 9 contacts where it was determinable had a window diameter of <0.35 mm. This suggests that either the cannula was a different size than it was thought to be, or a consistent artifact or interfering event occurred that changed the size of the window. This reduced window size could have a significant effect on charge density with possible implications for corrosion. Smaller than expected windows, based on gouge marks, were also seen in the in vitro electrodes.

The windows are cut through the silicone rubber sheeting to be symmetric relative to one another. In an ideal situation, the windows would be located in the center of the platinum foil contacts, however, slight misplacement or alignment of the contacts during fabrication can lead to the windows being offset. In these cuffs, the window in 15 of the contacts was offset from the center as determined with a qualitative visual assessment and using the gouge marks as indicators. This was somewhat less frequent than what was observed in the in vitro cuffs.

Figures 1.a, 1.b, and 2.a are examples of the excessive gouging and offset windows seen on these contacts.

Effects of Press Curing

In the in vitro cuff examination, it was found that the wires pressed into the contact, denting and in two instances actually tearing through the platinum foil. While 'dents' in the contacts were not frequently found in these cuffs and no tears were seen, the area overlying the wire exhibited a surface morphology change from the adjacent areas of the contact. This change in surface appearance in the area overlying the wires was also seen in the in vitro study. A cross-hatched striated appearance was seen in many contacts, similar to the markings seen on the wires on the backside, particularly in the weld area. These markings are clearly correlated with the wires on the backside, do not occur only in weldzones, and in some cases definitively outline the wires. The other characteristic marking resembled a large scale dimpling. Examples of the surface characteristics seen on these contacts is presented in Figure 2.

Spot Welding

The 7-strand wire leads were spot-welded onto the contacts using a hand fabrication method where quality of the weld was determined based solely on visual observations. In only 2 of the 54 contacts excised from these cuffs did the weld bond fail. This is in comparison to the 4 (of 36) contacts from the in vitro study where the weld bond failed. In that study it was found that the welds generally encompassed 5 or more wire strands. This was even more evident in these cuffs where over 70% of the welded contacts observed had 6-7 wires involved in the weld.

Fewer weld-related defects were noted in these contacts than in the contacts from the in vitro study. While large weld nuggets were present in some instances, no overlying surface disturbances were seen on the faces of these contacts. Occasional spots, primarily on the backsides, were found indicating failed weld attempts or other contact with the weld electrode. These spots exhibited a morphology consistent with one other and with similar spots found on the in vitro contacts.

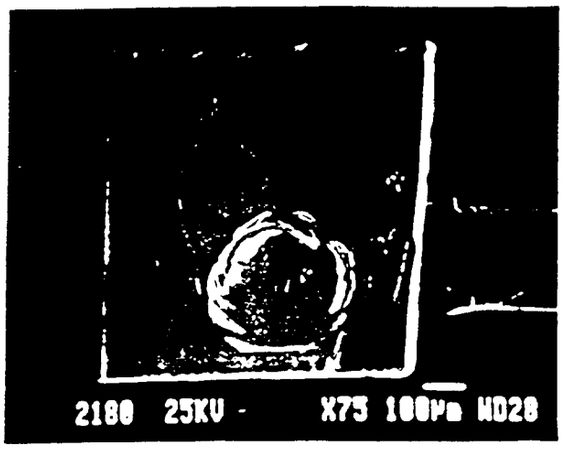
Evidence of Corrosion

The surface of the contacts was examined for evidence of corrosion, specifically corrosion pits. Unfortunately, many contacts or areas of contacts were covered with adherent material, despite the cleaning regimen. Because the contacts had been sputter coated, further ultrasonic cleaning of the contacts would likely not have been successful at removing any additional material.

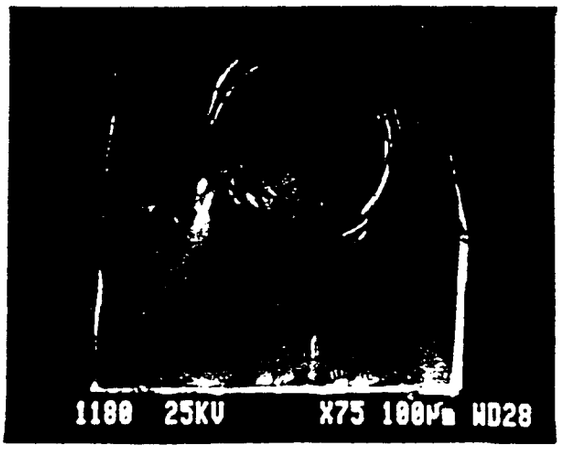
Isolated pits were observed on these contacts, but were found not only in exposed areas, but also in areas along the edges that should have been covered with silicone rubber sheeting and/or elastomer. These isolated pits and areas of parallel rows of pits were found on these contacts as well as the

in vitro contacts, as shown in Figure 3. No areas of concentrated pitting were found on these contacts. This is in contrast to the in vitro study, where extensive pitting was observed on contacts continually stimulated at 2 and 3 mA. It should be remembered that while the in vivo contacts were implanted for several months, they were not subjected to chronic stimulation.

The only pronounced incidence of corrosion was found on a single strand of wire on the back side of a contact. This strand, as shown in Figure 4, has a very honey-combed pattern of corrosion, which is not evident on the adjacent strands. Similarly, the weld zone of this contact shows no corrosion. In no other instances were the wires or weld zones of the contacts corroded.

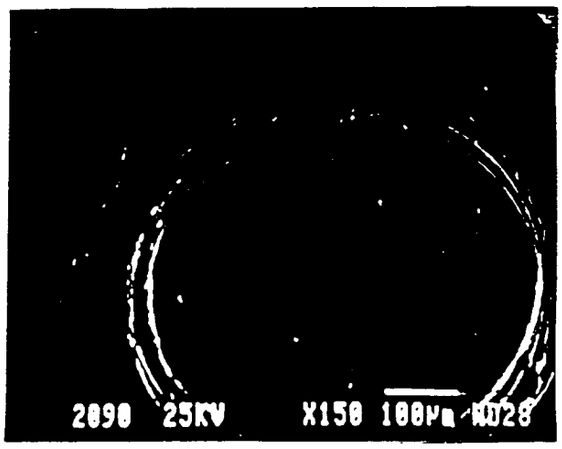


1.a: Photomicrograph of contact 2-180°, Cat #946.



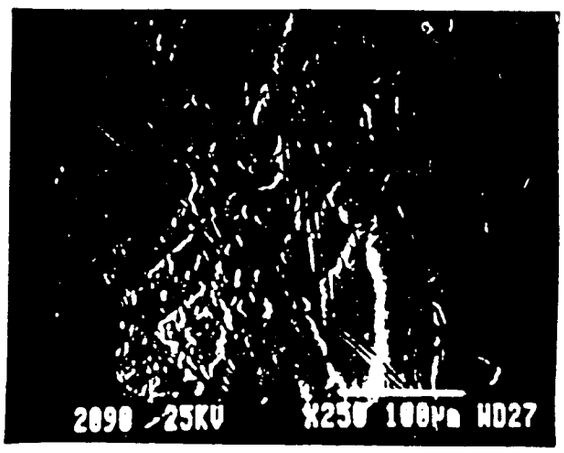
1.b: Photomicrograph of contact 1-180°, Cat #894.

Figure 1: SEM photomicrographs of the effects of hand cutting the contacts from a sheet of foil. The gouging and offset windows can be seen as well.



2.a: Photomicrograph of contact 2-90°, Cat #852.

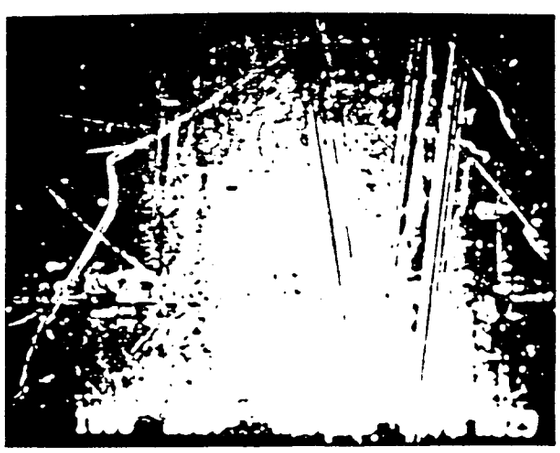
2.b: Photomicrograph of contact 1-180°, Cat #894



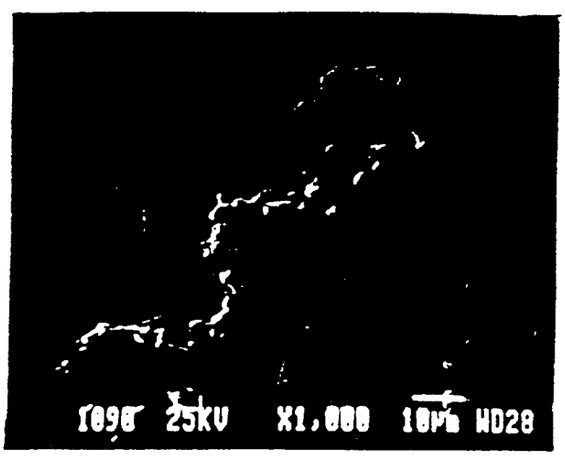
2.c Photomicrograph of contact 2-90°, Cat #865.

Figure 2: SEM photomicrographs of surface morphology in the area overlying the wires. Striations are shown in 2.a and dimpling is seen in 2.b and 2.c. Gouging from the window cutting tool can be seen in 2.a.

3.a: Photomicrograph of contact 0-90°, Cat #947.

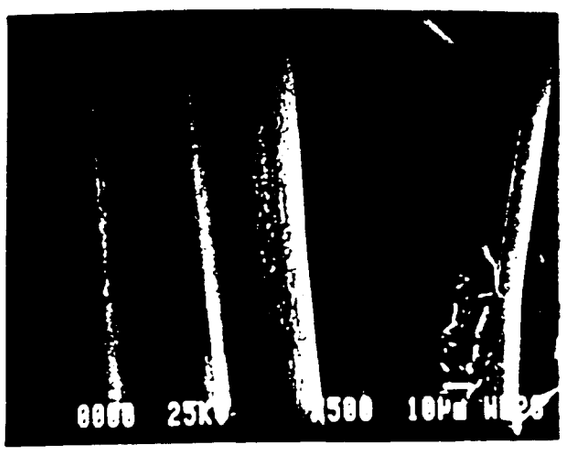


3.b: Photomicrograph of contact 1-0 , Cat #894.

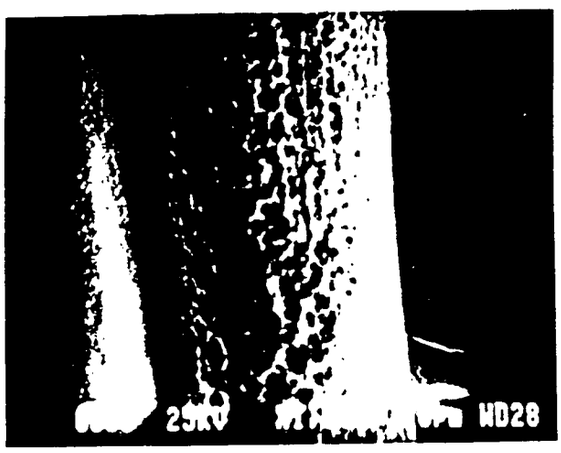


3 c Photomicrograph of contact 1-90°, Cat #947.

Figure 3: SEM photomicrographs of the pitting seen on the front face of several contacts. Isolated, random-patterned pits are shown in 3.a, while the pitting in 3.b and 3 c is oriented Pits similar to these were also seen on areas of the contacts that were not exposed



4.a: Photomicrograph of contact 0-0°, Cat #946.



4.b: Photomicrograph of contact 0-0°, Cat #946.

Figure 4: SEM photomicrographs of the only corroded area observed from the in vivo cuffs. The corrosion is isolated to a single strand of the wire. Figure 4.b is a higher magnification view of 4.a.